UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,210	08/29/2006	Sripriya Venkata Ramana Rao	AM-101457-1	5687

38199 7590 08/07/2009

HOWSON & HOWSON LLP / WYETH
501 OFFICE CENTER DRIVE
SUITE 210
FORT WASHINGTON, PA 19034

EXAMINER	
BARHAM, BETHANY P	
ART UNIT	**PAPER NUMBER**
1615	

NOTIFICATION DATE	DELIVERY MODE
08/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@howsonandhowson.com

Office Action Summary	Application No.	Applicant(s)	
	10/574,210	VENKATA RAMANA RAO ET AL.	
	Examiner	Art Unit	
	BETHANY BARHAM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89-112* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89-112* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/12/06, 10/3/06, 1/4/07, 3/21/07, 7/8/08, 7/16/08.

DETAILED ACTION

Summary

Receipt of IDS filed on 7/12/06, 10/3/06, 1/4/07, 3/21/07, 7/8/08, and 7/16/08 is acknowledged. Receipt of Applicant's Claim amendments filed on 2/5/09 is also acknowledged. Claims 89-112 are pending. Claims 89-112 are rejected.

NEW REJECTIONS

DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 89-111 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 7,544,370.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the both claim a method of producing, a product comprising a plurality of pantoprazole multiparticulates and pantoprazole multiparticulates with a spheroid core, initial seal coat, enteric coat, a diameter of 0.7-1.25mm, 25-30%microcrystalline cellulose, 4-6% polysorbate 80, 14-16% crospovidone, 0.5-2% hydroxypropyl methylcellulose, 5-8% sodium carbonate, and 1-2% water.

Claims 89-105 and 112 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 7,550,153 and claims 1-7 of U.S. Patent No. 7,553,498. Although the conflicting claims are not identical, they are not patentably distinct from each other because the both claim a method of producing, a product comprising a plurality of pantoprazole multiparticulates and pantoprazole multiparticulates with a spheroid core, initial seal coat, enteric coat, a diameter of 0.7-1.25mm, 25-30%microcrystalline cellulose, 4-6% polysorbate 80, 14-16% crospovidone, 0.5-2% hydroxypropyl methylcellulose, 5-8% sodium carbonate, and 1-2% water.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 89-90 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter,

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claim 89 states "pantoprazole salt or hydrate thereof" and claim 90 states pantoprazole sodium, pantoprazole magnesium or hydrate thereof" however there is no teaching in the specification of any hydrate of magnesium nor any other hydrate other than pantoprazole sodium sesquihyrate. This is a new matter rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 89-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,753,265 ('265) in view of US 5,997,903 ('903) or in the alternative.

The instant claims are drawn to pantoprazole multiparticulates having reduced release under gastric conditions and fast release at neutral pH, wherein each of said multiparticulates comprises: a spheroid core consisting of about 20 % w/w to about 45% w/w of a pantoprazole salt or a hydrate thereof and one or more excipients comprising about 25% to about 30% w/w microcrystalline cellulose, about 4% to about 6% w/w

polysorbate 80, about 14% to about 16% w/w crospovidone, about 0.5 to about 2% w/w hydroxypropyl methylcellulose, about 5% to about 8% w/w sodium carbonate, and about 1 to about 2 % w/w water; an initial seal coat comprising hydroxypropylmethyl cellulose on the spheroid core; and an enteric coat on the initial seal coat, wherein said multiparticulates have an average diameter of about 0.7 mm to about 1.25 ram.

- '265 teaches a dosage form of individual units or small beads, particles, pellets, etc of approximately 0.1 and 2 mm comprising a pantoprazole or salt thereof, surfactant, disintegrant, a separating layer, and an enteric coating made up of a copolymer of methacrylic acid and methacrylates (claims 1-3, 9-19 and col. 6, lines 7-9, 35-67-col. 7, lines 1-9 and 42-50).
- Examples 2-3, 10 and 12 specifically teach forming pantoprazole multiparticulate units of a size about 0.5 mm that are extruded, spheronized, and dried and then spray coating coated with a separating layer (which is hydroxypropyl methyl cellulose) and further an enteric coating (which is methacrylic acid copolymer). Example 2 also teaches polysorbate 80 and both examples teach including talc.
- '265 teaches a dosage form which can further comprise an overcoat on top of the enteric coating comprising hydroxylpropyl methyl cellulose and that the thickness of the overcoat is only limited by processing conditions (claim 8, col. 9, lines 6-30 and examples 9).
- '265 teaches that the enteric coating can be less than 60% of the total weight or at least 10 microns, preferably more than 20 microns thick (claim 6-7, col. 9, lines 1-5 and 45-48).

- '265 teaches that the core can contain hydroxylpropyl methylcellulose, microcrystalline cellulose, crospovidone, etc in the amounts as instant claimed (Examples 2-3, 10 and 12).
- '265 teaches the sodium salt of pantoprazole (col. 1, line 13-col. 3, line 42), sodium carbonate (col. 7, lines 15-20), hydroxypropyl methylcellulose, polyvinyl pyrrolidone, etc (col. 6, lines 54-65) and sodium lauryl sulfate, polysorbate 80 (col, 6, lines 64-65 and examples).
- '265 teaches a suspension of multiparticulates, a divisible dosage form and a press through blister package of units (claims 9-10 and 20).
- '265 teaches that benzimidazoles are known to be anti-ulcers and decrease gastrointestinal acid secretion, treat non-ulcer dyspepsia, GERD, etc (col. 1, lines 23-30) (meeting the limitations of instant claim 112).
- '265 does not teach the amount of sodium carbonate or the amount of water instant claimed in claim 89. Further '265 does not teach the specific sodium sesquihydrate form of pantoprazole but does generically teach sodium salts, and enantiomers.
- '903 teaches a pantoprazole sodium sesquihydrate 29% wt. of core with crospovidone, fillers/binders such as HPMC, sodium carbonate in 6.5% wt., etc with an initial HPMC coat and a outer Eudragit coat and that having 1.5% water content wt does not discolor/decompose the dosage form (col. 2, lines 1-5, 21-25, 60-67 and Example 1)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make and use the multiparticulate dosage form of '265 in combination with '903. A skilled artisan would know how to substitute the specific pantoprazole of '903 (sodium sesquihydrate) for the generic pantoprazole including sodium salt and enantiomers of '265 for treating GERD among other things with predictable results. Further a skilled artisan would know how to formulate a dosage form product of '265 incorporating the techniques of '903 to include 1.5% water and 6.5% sodium carbonate. One of ordinary skill in the art would know how to optimize the ranges of '265 in view of '903, as the MPEP 2144.05 states "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Claims 89-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,159,499 ('499) and US 5,753,265 ('265) in view of 5,997,903 ('903).

- '499 teaches a composition and method of making the composition comprising a) a core of an acid labile benzimidazole active principle, b) an intermediate layer and c) an enteric layer, provided that the active is not omeprazole (abstract, claim 1). '499 teaches pantoprazole and a size of about 1 mm (claims 3-4, 8-9 and Examples 21-26).
- '499 Examples 21-26 teach hydroxypropylcellulose, polysorbate 80, crospovidone, sodium lauryl sulfate, talc, etc and enteric coat of methacrylic acid copolymer. All examples were made in the same way of Example 1 which states

that the active suspension was sprayed onto a nuclei particle of 250 micron size and the core dried, and the temperature were kept below 45 degrees C, then the intermediate layer (hydroxypropylcellulose) added and then the enteric layer sprayed onto the core/intermediate layer.

- '499 teaches active principle in the amount of 2-50% (col. 7, lines 30-31 and 50-51).
- '499 teaches an intermediate layer of 5-30% (col. 7, line 25-26).
- '499 teaches an enteric coat comprising methacrylic acid copolymer (5-50 mg/per capsule), triethyl citrate (0-15 mg/per capsule), and talc (0-30 mg/per capsule, or 1-30% of the copolymer) (col. 7, lines 15-20 and 55-57).
- '499 teaches that the enteric coating can be 5-30% (col. 7, lines 27-28).
- '499 teaches that the microtablet core can contain hydroxylpropyl methylcellulose (1-100 mg/per capsule), crospovidone (0-50 mg/per capsule), polysorbate 80 or sodium lauryl sulfate (0-5.0 mg/per capsule), magnesium stearate (0.8-8), etc in the amounts as instant claimed (Examples 21-26; col. 6, lines 10-35; col. 7, lines 50-55).
- '499 teaches 40 mg of pantoprazole (Examples 6-8, and 21-26).
- '499 teaches multiple units in a capsule (claim 11, col. 7, lines 46-49).
- '499 teaches the active is useful for inhibiting gastric acid secretions in mammals and man, such as reflux esophagitis, gastritis, gastric ulcer, and duodenal ulcer, etc (col. 3, lines 44-54).

- '499 does not teach an example with microcrystalline cellulose, a suspension, foil pack or an final seal coat on the enteric coat, but does teach microcrystalline cellulose is a conventional excipient along with HPMC and crospovidone.
- '265 is taught above and teaches that the core can contain hydroxylpropyl methylcellulose, microcrystalline cellulose, crospovidone, etc in the amounts as instant claimed (Examples 2-3, 10 and 12).
- '265 teaches a dosage form which can further comprising an overcoat on top of the enteric coating comprising hydroxylpropyl methyl cellulose and that the thickness of the overcoat is only limited by processing conditions (claim 8, col. 9, lines 6-30 and examples 9).
- '265 teaches a suspension of multiparticulates, a divisible dosage form and a press through blister package of units (claims 9-10 and 20).
- '265 and '499 do not teach the amount of sodium carbonate or the amount of water instant claimed in claim 89. Further '265 or '499 do not teach the specific sodium sesquihydrate form of pantoprazole but do generically teach sodium salts, hydrates and enantiomers.
- '903 teaches a pantoprazole sodium sesquihydrate 29% wt. of core with crospovidone, fillers/binders such as HPMC, sodium carbonate in 6.5% wt., etc with an initial HPMC coat and a outer Eudragit coat and that having 1.5% water content wt does not discolor/decompose the dosage form (col. 2, lines 1-5, 21-25, 60-67 and Example 1)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of '499, '265 in combination with '903. A skilled artisan would know how to substitute a combination of excipients including microcrystalline cellulose of '265, into the dosage form of '499 which teaches HPMC and crospovidone with predictable results since '499 also teaches that microcrystalline cellulose is a conventional excipient. A skilled artisan would know how to substitute the specific pantoprazole of '903 (sodium sesquihydrate) for the generic pantoprazole including sodium salt, hydrates and enantiomers of '265 or '499 with predictable results. Further a skilled artisan would know how to formulate a dosage form product of '265 or '499 incorporating the techniques of '903 to include 1.5% water and 6.5% sodium carbonate. One of ordinary skill in the art would know how to optimize the ranges of '265 and '499 in view of '903, as the MPEP 2144.05 states "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." One of ordinary skill in the art would have been motivated to combine the references and have reasonable expectation of success since all teach pantoprazole multiparticulate dosage forms comprising a core, intermediate layer and enteric coatings that are superior to previous pantoprazole formulations. '265 teaches that the composition can be formulated successfully into a suspension or foil pack and further that a final overcoat can be added and is advantageous to prevent agglomeration, protect from cracking, etc (col. 9, lines 25-28).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham
Art Unit 1615

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635